TERUMO®

TERUMO MEDICAL CORPORATION

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Dockets Management Branch HFA-305
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

June 30, 2004

RE: Medical Device User Fees & Modernization Act of 2002 **[[Docket #02N-0534]]**
Section 301: Branding

To Whom It May Concern:

Terumo Medical Corporation is submitting herein, recommendations of medical device codes (FDA product codes) for consideration of waiver from compliance with Section 301 of the MDUFMA of 2002.

The product codes recommended for waiver from Section 301 are contained in the attached chart indicating the classification name, FDA product code, rationale for considering a waiver, and rationale against reuse where appropriate.

It is our opinion that "branding" as a general requirement is neither necessary nor does it provide information to the user that is not otherwise available in a clearer manner through other labeling. If "branding" according to Section 301 continues to be required, we request your consideration of these classes/codes of devices for waivers from the requirement.

Thank you for your consideration of this request.

Sincerely,

Sandi Hartka
Manager Regulatory Affairs

June 30, 2004
S.Hartka
Terumo Medical Corp
[02N-0534]

Product Type	Product Code	Rationale	
Set, Administration, Intravascular (including accessories, e.g. Injection plug)	FPA	[[Physical size and functionality compromise]]: Due to physical size, marking methods may compromise the integrity and/or functionality. Some of these devices are too small to add a visible marking.	Multiple uses of these devices raises other issues: effective cleaning of crevices containing blood & body fluids is nearly impossible, septums are not tested for multiple uses after reprocessing procedures, etc.
Tubes, Vials, Systems, Serum Separators (including luer adapter)	JKA	[[Physical size and functionality compromise]]: Due to physical size, marking methods may compromise the integrity and/or functionality. Some of these devices are too small to add a visible marking.	Using the device on more than one patient is not safe because cleaning blood or body fluids from this small cavity is virtually impossible to confirm. The integrity of the needle valve cannot be restored after the valve has been punctured multiple times and after being subjected to reprocessing procedures. Reprocessing will likely increase the probability of leakage from the valve and/or failure for the valve to recover the needle as intended causing leakage and increased blood exposure to user.
Set, Transfer (Blood, Plasma)	KSB	[[Functionality compromise]]:Due to physical size, marking methods may compromise the integrity, functionality of the devices.	
Wire, Guide, Catheter (guide wires, torque devices)	DQX	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner. These wires themselves can be less than 0.038" in diameter and nothing can be attached to them because they are designed to pass through catheters and cannot be obstructed.	
Catheter, Intravascular, Diagnostic	DQO	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner.	
Introducer, Catheter (includes obturators)	DYB	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner.	
Thermistor, Electronic, Clinical	FLL	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner.	
Catheter, Urological (includes accessories, e.g. guide wire)	KOD	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner.	
Endoscope and/or accessories (includes guide wires)	KOG	[[Physical size]] Due to the physical size of the area that can be marked, it would not be possible to mark the devices in a visible manner.	